

**Center for Drug Evaluation and Research - Office of Generic Drugs**  
**Quantitative Report**

**Table I**

**ORIGINAL APPLICATIONS**

	Jun-03	Jul-03	Aug-03	Sep-03	Oct-03	Nov-03	Dec-03	Jan-04	Feb-04	Mar-04	Apr-04	May-04	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
<b>-- RECEIPTS --</b>																
TOTAL ORIGINALS	36	37	36	26	38	44	102	54	25	51	40	38	527	44	43	36
AMENDMENTS	196	217	233	203	217	202	222	183	228	294	256	246	2697	225	265	183
- MAJOR	96	102	120	98	106	94	87	85	137	146	123	123	1317	110	131	92
- MINOR	100	115	113	105	111	108	135	98	91	148	133	123	1380	115	135	90
- FACSIMILE **	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
<b>-- ACTIONS --</b>																
APPROVALS	26	13	20	44	16	17	22	24	23	27	22	25	279	23	25	24
TENTATIVE APPROVALS+	14	7	4	14	7	5	11	8	11	10	7	7	105	9	8	6
APPROVABLE+	0	0	0	0	0	0	0	0	1	0	3	0	4	0	1	0
NOT APPROVABLE	83	65	78	52	65	69	88	66	76	86	88	83	899	75	86	62
REFUSE TO RECEIVE	8	7	2	4	9	5	1	13	13	12	4	5	83	7	7	5
WITHDRAWALS	24	6	10	3	2	7	24	19	10	5	4	7	121	10	5	14
- OF APPROVED	3	3	9	1	2	3	21	16	2	5	2	4	71	6	4	8
- OF UNAPPROVED	21	3	1	2	0	4	3	3	8	0	2	3	50	4	2	6
<b>-- REVIEW STATUS --</b>																
AWAITING OGD ACTION (TOTAL)***	470	498	524	506	515	533	607	625	586	626	632	625		562	628	449
AWAITING OGD ACTION (> 180 DAYS)***	28	47	60	58	65	54	73	69	65	56	57	58		58	57	31
AWAITING OGD ACTION (< 180 DAYS)***	442	451	464	448	450	479	534	556	521	570	575	567		505	571	419

\*\*\* In September, 1991, the Office of Generic Drugs started implementation of its Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. Review status figures reported since this date exclude suspended applications. As of May 31, 2004, 2 original application and 0 supplements were suspended.  
Upon completion of validity assessments, suspended applications may be returned to active pending status.  
+ Note: Approvable and Tentative approvals are counted as approvals subsequently when approved.

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**Table II**

**POST APPROVAL SUBMISSIONS TO APPLICATIONS (CHEMISTRY)**

	Jun-03	Jul-03	Aug-03	Sep-03	Oct-03	Nov-03	Dec-03	Jan-04	Feb-04	Mar-04	Apr-04	May-04	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
<b>--RECEIPTS--</b>																
ORIGINAL SUPPLEMENTS	147	260	372	185	167	238	244	240	223	422	342	264	3104	259	343	235
AMENDMENTS TO SUPPLEMENTS	238	313	395	218	257	267	235	279	310	507	384	281	3684	307	391	291
<b>--SUPPLEMENTAL ACTIONS--</b>																
APPROVALS	131	250	342	134	390	180	170	145	231	166	209	141	2489	207	172	203
APPROVABLE	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0
NOT APPROVABLE	92	84	100	68	57	66	93	86	122	79	107	89	1043	87	92	91
WITHDRAWALS	12	122	19	4	10	14	6	6	9	10	7	14	233	19	10	16
<b>--REVIEW STATUS--</b>																
SUPPLEMENTS AWAITING OGD ACTION (TOTAL) *	1300	1308	1285	1366	1213	1225	1298	1266	1334	1589	1719	1777		1390	1695	1258
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	54	46	66	61	66	61	71	87	88	99	71	75		70	82	56
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	1246	1262	1219	1305	1147	1164	1227	1179	1246	1490	1648	1702		1320	1613	1202

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**Table III**

**POST APPROVAL SUBMISSIONS TO APPLICATIONS (LABELING)**

	Jun-03	Jul-03	Aug-03	Sep-03	Oct-03	Nov-03	Dec-03	Jan-04	Feb-04	Mar-04	Apr-04	May-04	TOTAL	AVG LAST 12 MOS	AVG LAST 3 MOS	AVG PRIOR YEAR
<b>--RECEIPTS--</b>																
ORIGINAL SUPPLEMENTS	57	44	49	51	66	54	42	85	68	57	57	52	682	57	55	52
AMENDMENTS TO SUPPLEMENTS	70	64	65	51	84	42	48	96	77	74	73	75	819	68	74	69
<b>--SUPPLEMENTAL ACTIONS</b>																
APPROVALS	42	57	48	27	64	49	39	31	50	57	77	52	593	49	62	49
APPROVABLE	1	5	2	0	0	0	1	2	3	10	12	8	44	4	10	7
NOT APPROVABLE	7	6	8	7	3	12	11	7	9	12	10	12	104	9	11	11
WITHDRAWALS	1	5	8	6	2	5	5	1	2	3	1	3	42	4	2	3
<b>--REVIEW STATUS--</b>																
SUPPLEMENTS AWAITING OGD ACTION (TOTAL)	354	336	343	351	357	342	345	405	407	387	354	337		360	359	358
SUPPLEMENTS AWAITING OGD ACTION (>180 DAYS)	119	116	118	116	127	109	125	132	131	123	107	101		119	110	124
SUPPLEMENTS AWAITING OGD ACTION (<=180 DAYS)	235	220	225	235	230	233	220	273	276	264	247	236		241	249	234

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